

BONE FIXATION APPARATUS

INTRODUCTION

[0001] In certain orthopedic surgical procedures, it is necessary to secure multiple bones or bone portions relative to each other. For example, in spinal surgeries, the fusion of two or more vertebrae bodies is required to secure a portion of the spinal column in a desired position. This need may be the result of physical trauma from fractures or dislocations, degenerative diseases, or tumors.

[0002] One such spinal fixation procedure involves the attachment of a prosthesis or plate to the anterior side of the cervical portion of the spine. The procedure requires anteriorly accessing the spine and securing a prosthetic plate to the one or more cervical vertebrae. This allows fusion of the one or more cervical vertebrae in a particular orientation so to facilitate healing or to repair a condition of the patient.

[0003] Various fusion plates and plating systems are known for anteriorly fusing the cervical spine. Such plates and plating systems must meet several requirements that often are in conflict. For example, the requirements associated with spinal stability and system reliability over an extended period of use often conflict with the requirements of an easy to use implant. Strength requirements for a fusion plate tend to make the plate bulky and adversely effect intra-operative and postoperative viewing of the associate area of the spine. Additionally, it is desirable that the affected region of the cervical spine be easily

viewed using MRI or x-ray procedures to verify that the desired fusion of the cervical spine is complete and/or that the alignment of the cervical vertebrae is proper.

[0004] Plating systems are also required to ensure that bone screws do not loosen over time or back out from the plate, further complicating the design of anterior plating systems. It is further desirable to ensure that the bone screws placed into the vertebrae through the plating system do not loosen or back out from the plate without requiring additional surgical steps. Furthermore, locking mechanisms should adequately permit the removal of an associated bone screw when required, and allow sufficient angular freedom for bone screws relative to a plate.

[0005] It remains desirable in the pertinent art to provide an improved anterior cervical plating system that addresses all the requirements discussed above.

SUMMARY

[0006] The present teaching provide a bone fixation apparatus that includes a bone fixation plate having a fixation hole, and a modular bone fixation fastener received in the fixation hole. The bone fixation fastener includes a shaft member and an expandable head member. The shaft member has an outer cam that mates with a corresponding inner cam of the head member, such that upon rotation of the head member relative to the shaft member, the head member radially expands to prevent back out of the shaft member relative to the bone fixation plate.

[0007] The present teachings also provide a bone fixation apparatus that includes a bone fixation plate having a fixation hole, and a modular bone fixation fastener received in the fixation hole. The fixation hole has a first diameter in a plane generally parallel to an upper surface of the bone fixation plate. The fixation fastener includes a shaft member defining a shaft axis and an expandable head member carried by the shaft member. The expandable head member is rotatable about the shaft axis relative to the shaft member between a first position and a second position. In the first position the expandable head member has a maximum diameter that is smaller than the first diameter of the fixation hole, and in the second position the expandable head member has a maximum diameter that is greater than the first diameter.

[0008] The present teachings provide a bone fixation apparatus that includes a bone fixation plate having a fixation hole, and a modular bone fixation fastener received in the fixation hole. The bone fixation fastener includes a shaft member having a head-receiving first end with a multi-radius outer surface defining a cam lobe, and an expandable head having a multi-radius inner surface defining a cam lobe mating with the shaft cam lobe, such that upon rotation of the head member relative to the shaft member, the shaft cam lobe rotates out of alignment relative to the head cam lobe forcing the head member to expand radially to prevent back out of the shaft member relative to the bone fixation plate.

[0009] The present teachings also provide a method for fastening bone portions to each other. The method includes aligning a fixation plate for

attachment to the bone portions, aligning a first cam defined in a first portion of a modular fastener relative to a second mating cam defined in a second portion of the fastener, and inserting the modular fastener to one of the bone portions through a corresponding hole in the plate. The method further includes radially expanding a portion of the fastener against the hole, to prevent back out of the fastener.

[0010] Further areas of applicability of the present invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the preferred embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The present invention will become more fully understood from the detailed description and the accompanying drawings, wherein:

[0012] FIG. 1 is an exploded view of a fixation apparatus according to the present teachings;

[0013] FIG. 2a is an isometric view of a fixation plate for connecting two bone portions according to the present teachings;

[0014] FIG. 2b is a top view of a fixation plate for connecting three bone portions according to the present teachings;

[0015] FIG. 2c is a top view of a fixation plate for connecting four bone portions according to the present teachings;

[0016] FIG. 2d is a top view of a fixation plate for connecting five bone portions according to the present teachings;

[0017] FIG. 3 is sectional view of a head member according to the present teachings;

[0018] FIG. 4 is an isometric view of a head member according to the present teachings;

[0019] FIG. 5 is top view of a head member according to the present teachings;

[0020] FIG. 6 is an isometric view of a shaft member according to the present teachings;

[0021] FIG. 7 is an isometric view of another shaft member according to the present teachings;

[0022] FIG. 8 is a side view of the shaft member of FIG 6;

[0023] FIG. 9 is a side view of the shaft member of FIG 7;

[0024] FIG. 10 is a longitudinal sectional view of the shaft member of FIG. 8 taken along line 10-10;

[0025] FIG. 11 is a longitudinal sectional view of the shaft member of FIG. 9 taken along line 11-11;

[0026] FIG. 12 is an enlarged view of Detail D of FIGS. 8 and 9;

[0027] FIG. 13 is a sectional view of the Detail D of FIG. 12 along the axis 13-13;

[0028] FIG. 14 is a top view of a bone fixation fastener according to the present teachings;

[0029] FIG. 15 is a sectional view of the bone fixation fastener of FIG. 14 along axis 15-15;

[0030] FIG. 16 is sectional view of a detail of a bone fixation apparatus according to the present teachings;

[0031] FIG. 17 is an environmental view of a bone fixation system according to the present teachings shown with a tool for inserting and removing the bone fixation fasteners;

[0032] FIG. 18 is an enlarged view of the tool shown in FIG. 17; and

[0033] FIG. 19 is a plan view of the tip of the tool shown in FIG. 18.

[0034] FIGS. 20A-20C represent cross-sectional views of another embodiment according to the present invention selectively operable in dual modes.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

[0035] The following description of various embodiments is merely exemplary in nature and is in no way intended to limit the invention, its application, or uses.

[0036] FIG. 1 illustrates an exploded view of a bone fixation apparatus 100 according to the present teachings. The bone fixation apparatus 100 generally includes a bone fixation plate 102 and a modular bone fixation fastener 104. The bone fixation fastener 104 includes an expandable head member 106 and a shaft member 108 having a shaft axis "C". The bone fixation plate 102

includes one or more fixation holes 110 through which the bone fixation fastener 104 is inserted to be affixed to a bone portion.

[0037] FIGS. 2a to 2d illustrate examples of fixation plates 102 adapted for fixing together two to five bone portions 90, respectively, such as, for example, the vertebral bodies shown in FIG. 16. In the exemplary fixation plates 102 of FIGS. 2a-2d, the fixation holes 110 are arranged in pairs, two for each bone portion 90. Other arrangements are also within the scope of the present teachings. For example, one fixation hole 110 for each bone portion 90 may be provided, or more than two fixation holes 110 for each bone portion 90 may be provided. Each fixation hole 110 defines an inner surface 111, which may be spherical.

[0038] The fixation plate 102 can be shaped to conform to the bone portions 90 and have a curvature in one or two directions defined by a longitudinal axis "A" and a transverse axis "B", as shown in FIG. 1. It will be appreciated that the axes A and B, shown as orthogonal in FIG. 1, need not be so limited. Additionally, the fixation plate 102 can have different shapes and it can also be planar.

[0039] The fixation plate 102 can include a viewing window 114 to help monitor the location of any graft used in the fixation procedure and the progress of fusion in post-operative X-rays and MRI scans of the bone portions 90. The viewing window 114 can be defined between the sets of fixation holes 110 corresponding to contiguous bone portions or vertebral bodies 90, as shown in FIGS. 2a-2d. Additionally, the fixation plate 102 can include one or more

anchoring holes 116 for pre-fixation anchoring or alignment using standard fasteners, such as tacks or screws or just the shaft member 108 of the fixation fastener 104.

[0040] Referring to FIGS. 3-5, the expandable head member 106 is bounded by an open curved surface 118 defining a gap 120 and a central opening 122. The central opening 122 has an inner surface 124, and is adapted to receive the shaft member 108. The gap 120 increases the resiliency of the head member 106, such that head member 106 can expand from a relaxed position in which no pressure is exerted to the inner surface 124, to a pressurized position in which pressure is exerted on the inner surface 124 causing the gap 120 to widen. The inner surface 124 of the head member 106 defines an inner head cam 126 with one or more lobes 128. Each lobe 128 of the inner head cam 126 can be constructed, for example, by offsetting a radius of a segment of the inner surface 124 by a certain radial distance and then connecting the offset regions with variable radius curves.

[0041] FIGS. 6-13 illustrate shaft members 108 according to the present teachings. In particular, FIGS. 7, 9 and 11 depict views of a self-drilling shaft member 108, while FIGS. 6, 8 and 10 depict views of a self-tapping shaft member 108. The shaft member 108 includes an insertion portion 130 having threads respectively adapted for self-drilling or self-tapping, and a distal portion 132 adapted to be retained by the head member 106. A magnified view of the distal portion 132 is illustrated as Detail D in FIG. 12. A sectional view of the distal portion 132 is shown in FIG. 13. The distal portion 132 defines a outer

shaft cam 134 that has one or more lobes 136 adapted to mate with the lobes 128 of the inner head cam 126 while the head member 106 is in the relaxed position. In the relaxed position, the fixation fastener 104 can rotate freely and be seated in the fixation plate 102 at various angles relative to the plate 102.

[0042] When the head member 106 seats in the fixation hole 110 in the relaxed or unexpanded position, no pressure is exerted by the head member 106 to the inner surface 111 of the hole 110. The curved surface 118 of the head member 106 mates with the inner surface 111 of the fixation hole 110, such that the head member 106 can rotate freely relative to the inner surface 111 of the fixation hole 110 in the relaxed position. In the pressurized or expanded position, the expanded head member 106 is expanded toward the inner surface 111 of the hole 110.

[0043] Referring to FIG. 16, the head member 106 has a maximum diameter "D" which, in the unexpanded position of the head member 106, is smaller than an upper diameter "d" of the fixation hole 110 of the fixation plate, such that the head member 106 can be inserted through the fixation hole 110. The upper diameter d of the fixation hole is defined in a plane generally parallel to an upper surface 161 of the fixation plate. In the expanded position, the maximum diameter D is bigger than the upper diameter d of the fixation hole 110, preventing the head member 106 from backing out of the fixation hole 110 at the upper surface of the fixation plate.

[0044] In one application, the expanded diameter of the head member 106 is sufficiently large to press against the fixation hole 110. In this particular

application, the expanded head member 106 not only prevents the head member 106 from backing out of the fixation hole 110, but also arrests relative movement of the plate 102 and the fastener 108. This relationship is referred to as a "constrained relationship".

[0045] In another application, the expanded diameter of the head member 106 remains sufficiently large to prevent the head member 106 from backing out of the fixation hole, but is not so large to preclude movement between the fastener 108 and the plate 102. In this regard, the head member 106 is permitted to articulate relative to the fixation hole 110 and thereby the fastener 108 may articulate relative to the plate 102. This relationship is referred to as a "semi-constrained relationship".

[0046] With reference to the cross-sectional views of FIGS. 20A-20C, an embodiment of the present invention is illustrated which is operative in dual modes. In certain applications, the head member 106 and fastener 108 may be cooperatively configured to alternatively provide both a constrained mode of operation and a semi-constrained mode of operation. In this regard, the lobes 128 of the head member 106 may cooperate with the lobes 136 of the fastener 108 to provide dual modes of operation. Explaining further, the head member 106 may be rotated from a relaxed or unexpanded state (as shown in FIG. 20A) through a first rotation relative to the fastener 108 to expand the head member 106 to a first expanded diameter (as shown in FIG. 20B) and further rotated through a second rotation relative to the fastener 108 to expand the head member 106 to a larger second expanded diameter (as shown in FIG. 20C). Similarly, the

head member 106 may be rotated in a first direction relative to the fastener (e.g., clockwise or counterclockwise) to expand the head member 106 to the smaller first expanded diameter and further rotated in an opposite second direction to expand the head member 106 to the larger second expanded diameter.

[0047] In operation, the fixation plate 102 may be temporarily attached to the bone portions 90 with shaft members 108 or other fasteners through the anchoring holes 116. Each fixation fastener 104 is assembled by aligning the head member 106 with the shaft member 108 and placing the head member 106 over the shaft member 108. Each fixation fastener 104 seats on a countersunk portion 138 of the fixation hole 110 such that it can freely rotate, allowing the shaft member 106 to be placed in a desired orientation and be drilled or tapped into the bone portion 90. Once the shaft member 108 is anchored in the bone portion 90, the head member 106 can be rotated relative to the shaft member 108, such that the inner head cam 126 rotates out of alignment relative to the outer shaft cam 134 of the shaft member 108, causing the head member 106 to expand, thereby locking the fixation fastener 104 to the fixation plate 102 with compression forces therebetween.

[0048] Referring to FIGS. 14, and 17-19, the head member 106 can include slots or other engagement formations 140 for engaging the head member 106 with a first driver 158 to rotate the head cam 126 past the shaft cam 134 and cause the head member 106 to expand against the fixation hole 110, thereby locking the fixation fastener 104. The same driver 158 can be used to rotate the head member 106 in the opposite direction bringing the head and shaft cams 126

and 134 in lobe alignment to unlock the fixation fastener 104. The shaft member 108 can also have internal threads or other engagement formations 155 defined in an aperture 153 of the distal end 132, such that the shaft member 108 can be fastened to and unfastened from the bone 90 with a second driver 156 that has external threads 160 shaped to be inserted in the aperture 153 and engage the internal threads 155.

[0049] Referring to FIGS. 18 and 19, the first and second drivers 158 and 156 can be separate tools or can be combined in one tool 150 as follows. The first driver 158 is attached to a torque handle 154, and is hollow defining a bore 164. The second driver 156 is attached to a second handle 152 and passes through the bore 164. To insert the fixation fastener 104, the second driver 156 engages the internal threads 155 of the aperture 153 of the shaft member 108. The second handle 152 is rotated clockwise until the fixation fastener 104 is completely inserted into the bone portion 90 and the head member 106 is level with the fixation plate 102. The torque handle 154 is then rotated clockwise while the first driver 158 engages the slots 140 of the head member 106, causing the head member 106 to expand and lock the fixation fastener 104. To remove the fixation fastener 104, the reverse procedure is followed. The fixation fastener 104 is first unlocked by rotating the torque handle 154 counterclockwise to re-align the head cam 126 with the shaft cam 134 and return the head member to its unexpanded state, thereby loosening the fixation fastener 104 from the fixation plate 102. The second handle 152 is then rotated counterclockwise to remove the shaft member 108 from the bone 90.

[0050] It will be appreciated that the fixation apparatus 100 provides quick fixation and/or removal of the plate 102 to the bone portions 90 for bone repairs, while preventing the fastener 104 from backing out of the bone portions 90 after fixation. Furthermore, the fastener 104 can be readily oriented in a plurality of angles relative to the plate 102.

[0051] The description of the invention is merely exemplary in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the invention. Such variations are not to be regarded as a departure from the spirit and scope of the invention.